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FROST BROWN TODD, LLC
2200 PNC CENTER
201 E. FIFTH STREET
CINCINNATI, OH 45202

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| EXAMINER |
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LAURITZEN, AMANDA L

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| ART UNIT | PAPER NUMBER |
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3737

| SHORTENED STATUTORY PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE |
|----------------------------------------|-------------------|---------------|
| 3 MONTHS | 03/13/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/13/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dbell@fbtlaw.com
dfranklin@fbtlaw.com
rgaunce@fbtlaw.com

Office Action Summary

Application No.

10/803,700

Applicant(s)

WEISS, KENNETH L.

Examiner

Amanda L. Lauritzen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments filed 18 December 2006 have been fully considered but they are not persuasive.

1. Applicant has amended claims 1 and depending claims to specify that the image processing techniques are automated. Image processing techniques are inherently understood as automated by those skilled in the art, but nonetheless Examiner calls attention to the following support for automated detection of brain regions of interest in deCharms (US 6,996,261).

At col. 36, line 31, deCharms discloses that volume registrations [of regions of interest] can have a manual component and an automated component. At col. 44, lines 40-47, deCharms distinguishes manual selection of regions of interest from referencing to a standard anatomical atlas, stating that “*either* reference to a standard anatomical atlas, *or* using a manual search” may be performed (emphasis added). At col. 45, lines 43-56, regions or volumes of interest (including various landmarks previously cited by deCharms and claimed by Applicant) are identified “*either* manually, *or* in a fully or partially automated fashion” (emphasis added). Automated processing methods are explicitly disclosed at col. 47, line 7 – col. 48, line 19, in which the AC-PC reference line is a region of interest. These sections along with that which is known to those skilled in the art show that the method of deCharms supports automated determination of an AC-PC reference line by way of a processor and/or software.

2. Regarding claim 11, Applicant suggests that the nasion is an anatomical feature distinct from the hard palate. Examiner agrees and reminds Applicant that the passage in deCharms cited for identification of the nasion was exemplary and in support of locating *any region of interest* (as cited by deCharms at col. 44, lines 11-12 and Examiner in section (3) of the Office Action

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dated 10/02/2006). It would have been obvious to use the hard palate reference in the image in lieu of the nasion (or any other anatomical landmark) as Examiner conveyed in section (3) of the Office Action.

Being that the AC-PC reference line and the hard palate are both anatomical landmarks, Examiner understands that the reference line would inherently appear 12 degrees more extended than the hard palate in the image if the patient were positioned properly for the scan. Examiner further calls attention to section (6) of the prior Office Action in which Riew et al. was cited for, teaching that the hard palate is the most readily identifiable landmark of those examined in radiographic images.

3. Regarding claims 15 and 18, see section 1 above.

4. Applicant is suggested to contact the Examiner to schedule an interview for discussion of how the AC-PC reference line is being determined, to come to more explicit claim language with placement of the associated limitations in independent form for potential allowable subject matter (contingent upon an updated search). Prior to the interview, Applicant is advised to fax an Agenda detailing items for discussion directly to the Examiner at 571-273-4303.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed provisional application 60/455,969 filed on 18 March 2003 is acknowledged under 35 U.S.C. 120.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 6-10, 15-16 and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by deCharms (U.S. Patent No. 6,996,261).

Regarding claims 1-3, deCharms discloses a method comprising obtaining a midsagittal MRI diagnostic image of a patient's head, performing an image processing operation to determine the coordinates of a Talairach anterior commissure (AC) – posterior commissure (PC) reference line within the diagnostic image and defines a coordinate system of the diagnostic image with reference to the Talairach AC-PC reference line (col. 86, lines 14-17, lines 33-44 and line 65). Further disclosed is the prescription of a subsequent scan based on the identified AC-PC reference line and coordinate system (see col. 31, lines 44-52 in which regions of interest are defined and recalled for subsequent scans; also col. 38, lines 18-20 and col. 88 lines 10-11 for prescription of subsequent functional scans), as well as repeating of the image processing operation to determine current coordinates of the Talairach reference for accommodating

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changes in patient head position (col. 87, lines 2-12 in which coordinate determination accounts for patient rotation and/or translation during scanning).

At col. 36, line 31, deCharms discloses that volume registrations [of regions of interest] can have a manual component and an automated component. At col. 44, lines 40-47, deCharms distinguishes manual selection of regions of interest from referencing to a standard anatomical atlas, stating that “*either* reference to a standard anatomical atlas, *or* using a manual search” may be performed (emphasis added). At col. 45, lines 43-56, regions or volumes of interest (including various landmarks previously cited by deCharms and claimed by Applicant) are identified “*either* manually, *or* in a fully or partially automated fashion” (emphasis added). Automated processing methods are explicitly disclosed at col. 47, line 7 – col. 48, line 19, in which the AC-PC reference line is a region of interest. These sections along with that which is known to those skilled in the art show that the method of deCharms supports automated determination of an AC-PC reference line by way of a processor and/or software.

Regarding claim 4, the method of deCharms ‘261 includes obtaining at least two scout views (see col. 79, lines 27-49 for sagittal, coronal and axial displays that are initially obtained for comparison), identifying a midline feature to permit correction of roll and yaw (see col. 66, lines 18-41 in which movement metrics are determined relative to any anatomically defined structure with citation of roll and yaw correction), and obtaining a midsagittal MRI image based on identification of midline features (col. 86, lines 38-46 in which the midsagittal MRI image is obtained according to the midline anterior commissure feature).

Regarding claim 6-10, deCharms ‘261 discloses performing an image processing operation to search and identify the corpus callosum on a midline sagittal MR image (see corpus

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callosum presented in Fig. 2; also sagittal display of col. 79, line 47) and performing an image processing operation to identify the AC and PC relative to the selected landmarks and AC-PC line (col. 36, lines 38-44). Furthermore, deCharms discloses acquiring a roll and yaw corrected image (col. 66, lines 24-27) and referencing a template dataset with a known AC-PC institutional standard reference line and iteratively minimizing the difference between the sagittal brain image of the patient and the template dataset (col. 71, lines 33-40 with MNI reference atlas), and further discloses obtaining a previous scan of the same patient with a known AC-PC reference line (col. 36, lines 27-29 and lines 40-42). Furthermore, selecting a two-dimensional image section from a three-dimensional volume is disclosed (col. 39, lines 25-27 and col. 40, lines 7-10).

Regarding claims 15-16, deCharms '261 discloses a medical device comprising a scanner for obtaining a diagnostic image of a patient's head positioned therein, an image processor configured to determine coordinates of a Talairach AC-PC reference line within the diagnostic image that defines a coordinate system of the diagnostic image with reference to the AC-PC line (see scanner col. 25, line 62 and image/volume reconstruction software of col. 26, lines 1-2; see also software associated with Talairach mapping col. 45, lines 1-10). The image processor of deCharms further prescribes a subsequent scan based on the identified AC-PC reference line (see col. 88, lines 6-11 in which sagittal localization and anatomical scans are followed by functional scans) and includes repeat determination of current coordinates of the AC-PC reference for accommodating changes in patient head position since the previous position determination (see movement cancellation software of col. 90, lines 15-18).

Regarding claims 18-20, deCharms '261 further discloses a program configured to receive a diagnostic image of a patient's brain to determine the coordinates of a Talairach AC-

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PC reference line within the diagnostic image and to define a coordinate system of the diagnostic image with reference to the AC-PC line as well as a signal bearing media, with the program comprising at least one of a recordable media and a transmission-type media (col. 31 lines 41-52 in which the previously identified AC-PC region of interest is saved numerically to some form of memory). The program is disclosed to receive the diagnostic image comprising one from either a lateral CT image and a midsagittal MRI image (see col. 86 for mid-sagittal MRI scan in line 39 and the receiving program in line 50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over deCharms '261.

The disclosure of deCharms teaches all the features of the invention as substantially claimed, including performing at least one rapid scan to accentuate venous blood flow in a group consisting of a coronal, axial, and oblique scan of the patient's head (col. 20, line 32 for blood flow monitoring; also col. 79, lines 47-49 for one of a sagittal, coronal and axial display for physiological monitoring), and defining an attitude correction selected from a group consisting of roll and yaw correction corresponding to the selected plane for subsequent scans (see col. 52, lines 36-53 in which movement metrics are used to correct roll and yaw while assessing movement of the subject through acquisition with multiple scans).

While deCharms identifies many regions of interest for identification in patient scans, the disclosure is silent regarding the superior sagittal sinus reference; however, the invention of deCharms is not limited to identification of the anatomical landmarks listed in Fig. 2 that is cited in conjunction with neuroanatomical texts (col. 28, lines 37-39). Furthermore, deCharms discloses monitoring the blood flow in the vasculature of the brain at appropriate regions of interest (col. 92, lines 28-29). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated monitoring of the superior sagittal sinus in order to assess blood flow at the openings of the superior cerebral veins which converge at this region of the brain (Henry Gray's Anatomy of the Human Body, 1918, p. 652).

Regarding claim 11, deCharms '261 teaches all the features of the invention as substantially claimed but does not explicitly disclose the hard palate in the anatomical regions of interest cited in the disclosure; however, deCharms does cite using anatomical scans to locate any region of interest (col. 44, lines 11-12) and further discloses the nasion as an appropriate landmark in subject positioning (col. 35, lines 66-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated identifying the hard palate in the midline sagittal MRI image in order to gauge patient position in relation to a landmark that can be consistently recognized in midline sagittal MRI head scans. Furthermore, the AC-PC reference line being 12 degrees more extended than the hard palate would be inherent in proper patient positioning for a midline sagittal head scan.

4. Claims 12-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over deCharms '261 in view of Gouda (U.S. Patent No. 4,706,665).

All features of the invention as substantially claimed are taught by deCharms '261, but the disclosure is silent with regard to obtaining a lateral image view. However, in the same field of endeavor, Gouda '665 teaches obtaining a lateral CT scout image (col. 3, lines 17-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated obtaining a lateral scout image for the purpose of visualizing the scanner reference frame and coordinate lines of the scanner image (see Gouda '665 col. 3, lines 18-19 and lines 24-25).

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over deCharms '261 in view of Gouda '665 and Levin (U.S. Patent No. 5,546,472).

The modified invention of deCharms '261 includes all of the features of the invention substantially as claimed except for the calculation of an angle between the patient's hard palate and the identified AC-PC reference line. However, Levin '472 discloses a brain image coordinate mapping method based on identification of landmarks and their angular measurements (see col. 27, lines 34-37 and line 54 through col. 28, line 6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the angular measures of Levin '472 with the modified invention of deCharms '261 for the measure of an angle between the identified AC-PC midline and hard palate landmark for the purpose of providing a comparison parameter for several image scans (see Levin '472 col. 28, lines 3-6).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. George et al. (U.S. Application No. 2006/0173274) references the AC-PC line in determining the Talairach coordinates (para. 0035, lines 8-10). Kozel (U.S. Application No. 2006/0036152) references iteration in mapping of patient scans to the Talairach atlas (para. 0220, lines 11-17). Riew et al. "Diagnosing Basilar Invagination in the Rheumatoid Patient: The Reliability of Radiographic Criteria" *J. Bone Joint Surg. Am.* 83: 194-, 2001, for citation of the hard palate as the most readily identifiable landmark of those examined in radiographic images.

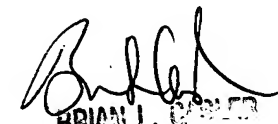
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


A. Lauritzen
03/05/2007


BRIAN L. GABLE
SUPERVISORY TECHNOLOGY CENTER